## MINUTES OF THE IDAHO STATE BOARD OF PHARMACY APRIL 5, 2012

## ISU/POND STUDENT UNION BLDG - POCATELLO, IDAHO

This meeting of the Board was held to conduct regular Board business.

Chairman Richard de Blaquiere, Pharm D, called the meeting to order on April 5, 2012 at 8:12 a.m. In attendance were Board members Berk Fraser, R.Ph.; Nicole Chopski, Pharm D.; Holly Henggeler, Pharm D.; and Mark Johnston, R.Ph., Executive Director; Jenifer Marcus, DAG; Jan Atkinson, Senior Compliance Officer; Fred Collings, Chief CS Investigator; Lisa Culley, Compliance Officer; Mike Brown, Compliance Officer; Gina Knittel, Compliance Officer; and Wendy Hatten.

Mr. Fraser entertained a motion to amend item number fifteen (15) in the agenda to an executive session, as authorized by Idaho Code 67-2345(b), in order to present Mr. Johnston's performance evaluation. Dr. Henggeler seconded the motion. The motion carried unanimously.

The minutes of the January 26, 2012 Board meeting were reviewed. Dr. Chopski motioned to approve the minutes with minor corrections. Mr. Fraser seconded. The motion carried unanimously.

Mr. Johnston presented the travel calendar. Mr. Johnston taught spring continuing education classes for Idaho State University, on March 4<sup>th</sup> in Boise, ID, March 18<sup>th</sup> in Pocatello, ID, March 28<sup>th</sup> in Lewiston, ID, and April 1<sup>st</sup> in Post Falls, ID. Mr. Johnston will teach continuing education classes tonight and tomorrow morning at the Eastern Idaho Regional Medical Center in Idaho Falls, ID, at St. Luke's Magic Valley on April 17<sup>th</sup> in Twin Falls, ID, at ISHP's spring meeting on April 29<sup>th</sup> in Boise, ID, and at the NW Pharmacy Convention on June 3<sup>rd</sup> in Coeur d'Alene, ID.

Mr. Johnston will be teaching continuing education to Idaho veterinarians on May 8<sup>th</sup> in Pocatello, ID, and on May 9<sup>th</sup> in Twin Falls, ID. Mr. Johnston envisions creating a continuing education program that covers 2011 dispensing prescriber law and new prescriber drug outlet law, incorporating the DEA's Practitioner Manual, as Idaho Code incorporates by reference federal inventory and record keeping requirements that practitioners must abide by. Mr. Johnston recently spoke to a group of Dentists in Caldwell, ID with Teresa Anderson. The presentation included PMP reporting, and Mr. Johnston anticipates future subject related classes.

Mr. Johnston attended the APHA meeting from March 9<sup>th</sup> through March 12<sup>th</sup> in New Orleans, LA. Ms. Lynette Berggren, contracted paralegal, attended the MPJE Question Writing Workshop on March 22<sup>nd</sup> through March 23<sup>rd</sup>, creating new questions to replace the 450 that were removed, subsequent to the promulgation of the new set of rules.

Mr. Johnston is scheduled to attend the ISU Dean's Advisory Council on April 14<sup>th</sup> in Meridian, ID, the Medicaid P&T committee meeting on April 20<sup>th</sup> and May 12<sup>th</sup> in Boise, ID, and the Annual NABP meeting from May 19<sup>th</sup> through May 22<sup>nd</sup> in Philadelphia, PA. Mr. Johnston, Mr. Fraser and Dr. Chopski plan to attend the Northwest Pharmacy Convention after the May 31<sup>st</sup> Board Meeting, both of which will be held in Coeur d'Alene, ID. Mr. Johnston and Teresa Anderson will be attending the Alliance of States with Prescription Monitoring Programs National meeting on June 3<sup>rd</sup> through June 6<sup>th</sup> in Washington, DC, to determine which interstate data sharing hub to utilize and how to best utilize our federal grant.

Via teleconference, Mr. Andy Snook presented three (3) stipulation and consent orders for the following;

Case number BOP 12-009, stipulation and consent order in the matter of Robert Degnan MD, involving violations of Idaho Code 37-2720, 37-2718(a)(4), and rule 496, for failing to properly maintain prescription drug orders, inventories, and records of controlled substances. The stipulation and order will expire one (1) year after the effective date so long as Mr. Degnan complies with the terms of the stipulation and consent order. For a minimum of one (1) year, Mr. Degnan shall not order prescriptions for controlled substances by phone and all orders for controlled substances must be in written, hard-copy form, or ordered through electronic prescribing. Mr. Degnan shall not order, handle, administer, or dispense any controlled substances for office use. Mr. Degnan shall not store or maintain any controlled substances, including samples of controlled substances in his office, home, automobile, or any other similar area.

Case number BOP 08-054, stipulation and consent order in the matter of Briant Burke, MD, involving violations of Idaho Code 37-2720, 37-2718(a)(4), and rule 496, for failing to properly maintain prescription drug orders, inventories, and records of controlled substances. The stipulation and order will expire one (1) year after the effective date so long as Mr. Burke complies with the terms of the stipulation and order. For a minimum of one (1) year Mr. Burke shall not order, handle, administer, or dispense any controlled substances including samples of controlled substances, for office use.

Case number BOP 12-014, stipulation and consent order in the matter of Kaye Harrison, R.Ph involving violations of Idaho Code 54-1726(a)(f) and Board rule 184.04, for failing to strictly follow the instructions of the person writing, making, or ordering a prescription as to refills. The stipulation and order will expire one (1) year after the effective date so long as Mr. Harrison complies with the terms of the stipulation and consent order. Mr. Harrison will be placed on probation for a period of one (1) year. Mr. Harrison shall pay an administrative fine in the amount of one thousand (\$1000.00) dollars within one hundred and eighty (180) days. Mr. Harrison must also submit a written plan of action to the Board, within thirty (30) days, explaining what he will do to ensure that he does not commit similar violations of the Board's statutes and rules.

Dr. Henggeler motioned to accept all three of the stipulation and consent orders as written. Mr. Fraser seconded. The motion passed unanimously.

Mr. Snook proposed that the Board adopt a consent agenda, default process as well as delegate authority to the Executive Director to appoint a Hearing Officer. The default process is used when a respondent fails to file answers within the allotted twenty one (21) days in response to an Administrative Complaint. The Attorney General's Office (AGO) will file an affidavit of the Executive Director supporting default. The Executive Director then issues a Notice of Appointment of Hearing Officer, designating General Counsel (GC) as the hearing officer, for preliminary procedures and also provides the GC with the Administrative Complaint. The AGO then drafts and provides the GC with a Notice of Proposed Default Order and a Default Order. The GC then sends the Notice of Proposed Default Order and the Default Order to the respondent who has seven (7) days to contest entry of the Default Order. Assuming there is no response, the GC enters Default Orders and the AGO presents proposed Findings of Fact, Conclusion of Law and a Final Order, based upon default, to the Board for consideration. In the instance where there is a response, depending on the case, there could be a hearing or a separate hearing officer process. Dr. Henggeler motioned to adopt the default process. Mr. Fraser seconded the motion. The motion passed unanimously.

The Agenda item regarding Jennifer LaPlante was vacated.

Julie Gleason R.Ph, V.P. of Pharmacy Services, InstyMeds and Dorsie Sullenger, R.Ph. of Madison Memorial Hospital, Medical Director of Pharmacy, presented the InstyMeds Dispenser, a fully automated physician medication dispensing system. The dispenser has a touch screen, credit card reader and a telephone with a direct dial to the 24/7 call center. The calls are handled by a pharmacy technician. 97% of the calls are benefit driven, if there is a clinical question there is a pharmacist on call 24/7. The dispenser is a steel cabinet that weighs approximately 2000lbs. The patient obtains the prescription using a printed voucher that has a one time use 7 digit code and the patient's date of birth as a pin number. There is a triple part barcode process that takes place in filling the prescription to assure the correct patient and medication is dispensed. The prescription is dispensed with a printed label. InstyMeds has the ability to provide dispensing reports, physician and patient reports, lot numbers and expiration dates as well as report to Prescription Monitoring Programs. All of the drugs that are supplied in the InstvMeds machines are supplied by Redpharm Drug, a VAWD certified and registered wholesaler. Ms Gleason submitted a request for waiver or variance, as per Board rule 013 to allow the InstyMeds Dispenser to be utilized within Idaho, hospital, emergency rooms. Mr. Sullenger spoke specifically about the challenges of emergency room dispensing at Madison Memorial Hospital, including limited community pharmacy hours of operation, the volume of emergency room dispensing, and emergency room, registered nurse, error rates. Mr. Johnston corrected Ms. Gleason's presentation, stating that Idaho indeed had lengthy wholesale distribution law, and Ms. Gleason confirmed that they could provide required distribution pedigrees, as they are performing repackaging of products used within the Dispenser. Dr. de Blaquiere preferred initiating rulemaking as opposed to approving the waiver or variance. Dr.

Chopski obtained Board assurance that rulemaking efforts would indeed be considered by the Board. After a lengthy discussion that involved numerous rules changes that would be required to allow such practice, the Board directed Mr. Johnston to initiate rule promulgation that would allow the InstyMeds Dispenser to be utilized in emergency rooms, for consideration at upcoming Board meetings.

Dr. de Blaquiere called the meeting back to order after a short break.

Mr. Snook, via telephone, represented the Board for case number BOP 11-049: a reinstatement hearing regarding Keith Scheuermann, MD, who was present at the hearing. Mr. Scheuermann had voluntarily surrendered his CS registration, and pursuant to his delegated authority, Mr. Johnston subsequently issued a Board order revoking Mr. Scheuermann's CS registration. Recently, the Board of Medicine (BOM) issued an order to reinstate Mr. Scheuermann's license with restrictions. The Board staff recommended an order that basically mirrored the BOM's order, reinstating Mr. Scheuermann's CS registration with the same BOM restrictions. Dr. Chopski motioned to accept the reinstatement order as written. Dr. Henggeler seconded the motion. The motion passed unanimously.

Mr. Johnston requested delegated authority to prevent delays in reinstating a revoked CS registration in a situation where the Board is basically mirroring an amended order from another licensing board. Dr. Chopski requested that the Board continue to be notified when Mr. Johnston uses his delegated authority. The Board requested a list of their previously authorized delegated authority and granted unanimous consent for the current request.

Mr. William Cover, R.Ph, Corporate Manager, Pharmacy Affairs, presented the Walgreens Well Experience. Some key features of their new pharmacy model include the pharmacist being located at a patient level desk that is highly accessible and outside of the production area of the pharmacy, a private consultation and administration room adjacent to the pharmacist desk, the final check completed by the pharmacist at a patient accessible desk utilizing a high definition digital imaging filling process, a prescription refill kiosk, and personnel that serve as a health guide in navigating the Well Experience. There is centralized support for many administrative tasks such as data entry, physician and patient phone calls, and third party adjudication. The Board discussed the proposed, non-resident, non-institutional, centralized support centers, discussed several concerns with Mr. Cover, and ultimately directed Mr. Johnston to add such facilities to the Board's draft, non-resident, drug outlet law, expected to be discussed in full at the next meeting of the Board. Mr. Johnston requested model language from Mr. Cover.

During Inspector Q&A, Jan Atkinson requested clarification of new rule 105, regarding documentation of counseling. Ms Atkinson specifically asked if the proof of sufficient evidence of counseling must include patient documentation, as opposed to or in addition to, pharmacy documentation. After much discussion, the Board confirmed earlier deliberation that lead to a purposefully vague requirement in rule, thus allowing a

pharmacy to make a business decision as to the composition of the documentation. The Board warned that pharmacy only documentation complied with the rule, but might not be sufficient proof in a contested case, thus suggesting additional patient documentation.

Also during Inspector Q&A, Mr. Johnston introduced Jeff Dahlke, Health & Wellness Market Director for Wal-Mart, who presented the Wal-Mart LEP Customer program. The program is administered by an outside agency that provides interpretative services via the phone. They also provide a fluency assessment program for pharmacy associates to become certified as interpreters. The fluency assessment program requires pharmacy associates to have the language competency of a native speaker. The inspectors questioned the program's legality. After short discussion, the Board applauded efforts to communicate with patients who did not speak English and did not believe the program circumvented counseling law.

Dr. de Blaquiere called for Public Comment. There was no public comment.

Dr. de Blaquiere called the meeting to order after a lunch break.

Mr. Johnston presented the Board's financial report:

- Comparisons of budget to expenses indicate that 69% of the fiscal year is completed and approximately 63% of the budget has been used.
- The Board office is waiting for the Department of Justice to specify how the grant can be spent, due to the creation of NABP's Interconnect program.
- The Board has been appropriated a new full time position that will assist with the provision of unsolicited, PMP reports.
- The legislature approved a two percent (2%), across the board, pay raise for state employees.
- A report for proposal was completed, resulting in a new two (2) year contract with Southworth Associates, administrator of the Boards pharmacy recovery network.
- The Board office is in the process of entering into a contract with the Idaho Lottery Commission to share data lines services creating more data space for improved storage and response time.

Dr. de Blaquiere inquired as to the increase in the number of controlled substance, registrant, stipulation and consent orders issued in the past year. Fred Collings, Chief Controlled Substance Investigator explained that he reviews monthly reports from wholesale distributors, such as Henry Schein, for possible discrepancies. If discrepancies are found, a two year order history is requested to further investigate. Such further investigation has uncovered the issues detailed in the Board's orders. Mr. Johnston is writing newsletter articles, highlighting such issues, for use by the medical licensing boards. Additionally, after presenting at an open, public meeting of the BOM, Mr. Johnston has received confirmation that the BOM will add parameters to their orders that will restrict office use of controlled substances, when appropriate.

Mr. Johnston presented final House and Senate bills:

HB502 – The Board initiated several changes to the schedules of controlled substances in sections 37-2705 through 37-2713, Idaho Code, which included mimicking recent changes to the DEA's schedules including carisoprodol. Additionally, the 2011 language that scheduled the known ingredients collectively referred to as "Spice" was strengthened to include more substances, pursuant to an amendment, and chorionic gonadotropin (hcg) was de-scheduled.

HB503 – Amends section 54-1733, Idaho Code, to establish circumstances where a prescriber may perform certain activities for a patient with whom the prescriber does not have a prescriber-patient relationship. Seven exceptions listed by the bill include: 1) writing admission orders for a newly hospitalized patient 2) writing a prescription for a patient of another prescriber for whom the prescriber is taking the call 3) writing a prescription for a patient by another licensed practitioner with whom the prescriber has a supervisory relationship 4) writing a prescription for a medication on a short term basis for a new patient prior to the patient's first appointment 5) in an emergency situation where life or health of the patient is in imminent danger 6) in emergencies that constitute an immediate threat to the public health and 7) if a prescriber makes a diagnosis of a sexually transmitted disease in a patient, the prescriber may prescribe or dispense antibiotics to the infected patient's named sexual partner or partners for treatment of sexually transmitted disease. The bill was run by the Idaho Medical Association, with the support of many entities, including the Board of Pharmacy.

HB No. 569 – Amends section 37-2726 to further clarify that PMP data submission is only required for human dispensing and not animal dispensing. The bill was sponsored by a Representative Loertscher, whose son is a veterinarian.

SB1309 – Section 37-3303, Idaho Code, was amended to revise provisions relating to maximum quantities of pseudoephedrine that can be purchased. Chapter 33 Title 37, Idaho Code, was amended by adding a new section, 37-3303A. The Board has been tasked with implementing a real-time electronic sales tracking system to monitor the non-prescription sale of PSE products. The system must also record purchase data required by federal law. The electronic system must be capable of generating stop sale alerts, for quantities in excess of the legal limits, and a retailer must not sell PSE products if receiving a stop sale alert. Access to the electronic system must be free of charge. The Board may provide a retailer exemption in extremely limited situations. This new section also provides for use of records gathered, authorizes the Board of Pharmacy to promulgate and enforce rules, and limits the liability of retailers. The Bill was sponsored by Senator Broadsword and supported by the Board of Pharmacy.

SB1292 addresses concerns over the purchase of controlled substances for use in the execution of a prisoner.

S1241would have mandated that a prescriber access PMP data prior to prescribing a CS to a patient for the first time and annually thereafter, but it did not receive a hearing. A prescription drug abuse task force has been assembled instead.

S1366: Negotiated rulemaking is now required, unless the promulgation fits within defined exceptions. Such requirement is satisfied by printing a notice of negotiated rulemaking in Idaho's Administrative Bulletin, scheduling such negotiation at an open, public meeting of the Board. Mr. Johnston intends to print as such in the May and August publications for the May and August Board meetings. A meeting has been scheduled where the Department of Administration, Division of Rules will provide further guidance.

HB0629 would have required that State agencies hire a hearing officer from an approved list maintained by the Department of Administration, as opposed to stipulating or hearing disciplinary cases ourselves. The bill was withdrawn by the sponsors, but is expected to be heard again next year, revised to pertain only to cases where the Board chooses to utilize a hearing officer.

HB 439 - Amends section 37-2726, Idaho Code, to allow interstate data sharing; provide for violations and penalties relating to the failure to safeguard certain user accounts, login names, and passwords; to provide that the board may block certain access; and amending section 37-2730A, Idaho Code, to clarify that the board may provide unsolicited reports to pharmacists and practitioners.

Mr. Johnston reported that, pursuant to the Board's direction at the last open, public meeting, he convened a meeting of the Idaho Pharmacy Leadership Council (IPLC) to discuss the written requests of the Pharmacy Alliance, as well as Bob Comstock's ratio request. After considering each line item of the requests individually, IPLC unanimously voted to not support any of the requests. The Board accepted IPLC's decision and instructed Mr. Johnston to communicate the vote of no support to the two requesting entities.

Mr. Johnston noted that a copy of the Uniformed Controlled Substance Act was included in the agenda binder, complete with his Track Change comments, detailing initial direction on a project to rewrite the Act. The Board believes the project to be too large to complete in time for the 2013 legislature. Additionally, slight modifications to the draft of the re-writing of the out of state mail service pharmacy act were presented by Mr. Johnston, pursuant to the Board's direction at the last open, public meeting. The Board is hopeful to present such a project to the 2013 legislature, realizing much work

remains. Lastly, Mr. Johnston noted that a final version of the rules approved by the 2012 legislature, including a final glossary, was included in the agenda packet.

A letter from Larry Weiner, MD and a response letter from Ms Atkinson were discussed. Dr. Weiner is requesting rule promulgation that would allow certain drug product substitution when a prescribed drug is unavailable. For example, he would like, without required prescriber contact, for pharmacies to dispense two (2) tablets of a five (5) mg strength, if such strength is available and the prescribed ten (10) mg tablets are not available. The Board directs Mr. Johnston to create draft language for consideration.

Mr. Johnston read a letter sent to the Governor's office from a prospective public member for the Board's current vacant position.

A Board meeting date was tentatively set for Friday November 2, 2012 in Boise.

Mr. Fraser motioned to go into executive session. Dr. Henggeler seconded the motion. All in favor. Dr. Chopski motioned to end executive session and adjourn the Board Meeting. The motion passed unanimously. Executive session and the Board Meeting ended at 3:27 p.m.